§ 12.22 Labels; samples.

Each package of such products imported for sale, barter, or exchange shall be labeled or plainly marked with the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected to yield their specific results. From each lot of product the port director shall select at random at least two final containers. The random sample together with a copy of the associated documents which describe and identify the shipment shall be forwarded to the Director, Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, Md. 20014. For shipments of 20 or less final containers, samples need not be forwarded, provided a copy of an official release from the Bureau of Biologics accompanies each shipment.

[T.D. 69–201, 34 FR 14328, Sept. 12, 1969, as amended by T.D. 82–145, 47 FR 35476, Aug. 16, 1982]

§ 12.23 Detention; examination; disposition.

(a) Port directors shall detain all importations of unlicensed viruses, therapeutic serums, toxins, antitoxins, and analogous products, and arsphenamines or its derivatives (or any other trivalent organic arsenic compound) for the treatment or cure of diseases or injuries of man pending examination by the Director, Bureau of Biologics, unless satisfied from evidence furnished at the time of entry that the products are intended solely for purposes of controlled investigation and not for sale, barter, or exchange, as evidenced by a copy of a filed ''Notice of Claimed Investigational Exemption for a New Drug,'' pursuant to §312.1 of the Food, Drug, and Cosmetic Act Regulations (21 CFR 312.1), or are being imported under the short supply provisions of §601.22 of the Public Health Service Regulations (42 CFR 601.22).

(b) If the shipment is imported for sale, barter, or exchange and is found by the Director, Division of Biologics Standards, to be admissible, the port director shall release it upon receipt of a report from him that the shipment is admissible.

(c) If the Director, Division of Biologics Standards, reports that the shipment was found upon examination not to conform to the law and the regulations, the port director shall not release the shipment but shall permit the exportation or destruction thereof under Customs supervision at the option of the importer.

(d) Shipments of such products for use in the treatment of man but made from or with material of animal origin other than human, shall, unless accompanied by a Department of Agriculture, Veterinary Services, Animal and Plant Health Inspection Service (APHIS) permit, be detained until proof is presented to the port director that their importation is not prohibited under 9 CFR part 94 or part 122.

[T.D. 69–201, 34 FR 14328, Sept. 12, 1969, as amended by T.D. 82–145, 47 FR 35476, Aug. 16, 1982]

DOMESTIC ANIMALS, ANIMAL PRODUCTS, AND ANIMAL FEEDING MATERIALS

§ 12.24 Regulations of the Department of Agriculture.

(a) The importation into the United States of domestic animals, animal products, and animal feeding materials is subject to inspection and quarantine regulations of the Department of Agriculture, Customs officers and employees are authorized and directed to perform such functions as are necessary or proper on their part to carry out such regulations of the Department of Agriculture.

(b) Inspection by an inspector of the Animal and Plant Health Inspection Service, Veterinary Services is required for all horses, cattle, sheep, other ruminants, and swine as a prerequisite to their entry from any foreign country. Orders listing the ports designated as quarantine stations for the inspection and quarantine of animals will be issued by the Secretary of Agriculture, with the approval of the Secretary of the Treasury, whenever conditions warrant.

(c) The entry of domestic animals may be made, but shall not be required, before the expiration of the quarantine period. Such animals, if not entered at the time of arrival, shall be considered as under general order while under quarantine and shall not be released